Remarks

Claims 1-22 are pending and subject to a number of election of species requirements. Claim 18 does not read on the elected active species and has been withdrawn from consideration. Claim 1 has been amended to provide that the nucleation inhibitor is uniformly dispersed in the aqueous suspension as described in the passage bridging pages 4 and 5 of the Specification. Claim 19 has been amended to limit the thickening mixture to the materials shown in Example 2. No new matter has been added.

The Examiner rejects claims 1-16 and 19-22 under 35 U.S.C. 103 as being unpatentable over U.S. Patent No. 5,980,882 ("Eichman") in view of U.S. Patent No. 5,374,659 ("Gowan, Jr.") and U.S. Patent No. 5,356,467 ("Oshlack et al."). The Examiner rejects claim 17 under 35 U.S.C. 103 as being unpatentable over Eichman in view of Gowan and Oshlack and further in view of U.S. Patent No. 5,834,019 ("Gergely et al."). Applicants respectfully traverse these rejections.

The Examiner cites Eichman as showing drug resin complexes that are stabilized by chelating agents, such as EDTA. Applicants restate and incorporate by the reference the arguments relative to Eichman from the prior response. The Examiner further asserts that Eichman fails to teach the specific active agent, thickener and nucleation inhibitor as claimed. The Examiner cites Oshlack as teaching a stable aqueous dispersion that comprises one or more pore formers, including starch, modified starch, gums and cross-linked PVP. The Examiner alleges that the gums include xanthan gum corresponding to the claimed thickener and cross-linked PVP corresponds to the claimed nucleation inhibitor.

Oshlack is directed to controlled release coatings that contain zein. The coatings are applied to particles that are subsequently used in **solid dosage forms** (tablets). Col. 4, lines 36-39 and examples. These controlled release coatings can optionally further include pore-former polymers, which the Examiner indicates is represented by cross-linked PVP.

Claim 1 has been amended to provide that the nucleation inhibitor is uniformly dispersed as taught on page 4 of the Specification. The nucleation inhibitor of the present invention is dissolved within the overall claimed aqueous suspension. The cross-linked PVP in Oshlack is used as one component in the coating of a particle in a solid dosage form to produce pores in the coating only when ingested and allow for release of the active ingredient. The purpose for using

cross-linked PVP in Oshlack is not equivalent to or a substitute for use of PVP as a nucleation inhibitor as claimed herein. The cross-linked PVP in Oshlack is not uniformly dispersed in an aqueous suspension dosage form because the particles are meant for use in tablets. The PVP component in Oshlack does not perform the same function as the PVP in the claimed formulations.

Recently issued guidelines to Examiners regarding combinations of references emphasize that substituted elements must perform the same function and the results of the combination must have been predictable to those skilled in the art. Federal Register, Vol. 72, No. 195, pp. 57526-57535. Pore formers perform their role only when ingested to enable the release of active through a coating, whereas the nucleation inhibitor of the present invention prevents crystal agglomeration. There is no reason to believe that the pore formers of Oshlack would function to prevent crystal agglomeration in aqueous suspensions. Consequently, the cross-linked PVP in Oshlack cannot be combined with the drug resin complex of Eichman to arrive at the instantly claimed invention. The Examiner has failed to make a prima-facie showing of obviousness. Applicants request that the Examiner reconsider and withdraw his obviousness rejections based on Eichman, Oshlack and Gowan.

Claim 19 has been amended to provide that the thickener component comprises the materials, xanthan gum and pregelatinized starch, used in Example 2. The samples of Example 2 were tested for viscosity and pH according to methods described therein with results shown in Figures 1 and 2, respectively. Results indicate the addition of EDTA in the formulation has a stabilizing effect on both viscosity and pH. Applicants submit that this discovery is sufficient to place claim 19 and its dependent claims in condition for allowance.

Applicants request that the Examiner contact the undersigned representative in the event that minor amendments will further prosecution.

Respectfully submitted,

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